**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF OHIO**
**EASTERN DIVISION**

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| **IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION** | ) | **MDL 2804** |
| | ) | |
| | ) | **Case No. 1:17-md-2804** |
| **THIS DOCUMENT RELATES TO:** | ) | |
| | ) | **Judge Dan Aaron Polster** |
| *The Montgomery County Board of County Commissioners, et al. v. Cardinal Health, Inc., et al.,* Case No. 1:18-op-46326 ("*Track Seven*") | ) | **OPINION AND ORDER REGARDING PLAINTIFF'S MOTION TO EXCLUDE OPINIONS OF PATRICK J. MARSHALEK** |

Before the Court is Plaintiff Montgomery County's Motion to Exclude Certain Opinions of Defense Expert Dr. Patrick J. Marshalek, MD (docket no. 4885). Kroger filed a response in opposition (docket no. 4949) and the County filed a reply in support (docket no. 4962). For the reasons stated below, Plaintiff's Motion is **GRANTED in part** to the extent described below, but otherwise **DENIED**.

Dr. Marshalek is a physician with board certifications in psychiatry and addiction medicine. He is an associate professor at West Virginia University School of Medicine's Department of Behavioral Medicine and Psychiatry, Department of Anesthesiology and Department of Neuroscience. Marshalek has published articles on opioid treatment and on opioid use disorder. He has limited professional experience with pharmacies, having volunteered during medical school in a pharmacy – an experience he does not recall with great clarity. Over the past several years, Marshalek has served as a litigation consultant in several cases for the DEA, the Maryland Attorney General, and the West Virginia Board of Medicine, primarily in cases against physicians.

Marshalek's expert report consists of four pages of opinions covering:

- The delivery of healthcare, including opioid pharmaceuticals, in the United States;

- The role of clinicians in writing opioid prescriptions, including informed consent;
- The role of pharmacies in dispensing opioids, including pharmacists' "scope of practice," "situation downstream from the medical decision making," and their "disadvantage with respect to determining if the opioid prescription was legitimate, written in good faith, inside the course of medical practice and within the scope of a prescriber;"
- The complexity of addiction and the difficulties facing the healthcare system in dealing with it;
- The "gateway theory," which he finds "unsubstantiated and controversial;"
- The unintended consequences arising from the "shifting . . . approach to treating pain at all costs;"
- The role of the federal government, including the Drug Enforcement Administration (DEA) and Federal Drug Administration (FDA), in deciding "the overall amount of opioid [sic] allowed to be manufactured each year" and requiring "certain medications to have what are known as REMS (Risk Evaluation and Mitigation Strategies);"

Marshalek concludes his report by opining that

> [t]he federal government could have limited the amount of opioids manufactured, changed how opioids were scheduled, changed the FDA indication of opioid use, used [Risk Evaluation and Mitigation Strategies] or waiver requirements, or limited the manufacturer's ability to influence prescribing through marketing communication and other activities. To suggest that community pharmacies, or the

> pharmacists working for those community pharmacies, are responsible for the crisis of addiction is wrong.

*See* Motion Ex. B, Marshalek Report at 1-4 (Docket no. 4885-2).

**Legal Standard**

The Court incorporates by reference the applicable *Daubert* legal standards set forth in its *Track One Daubert Order Regarding Dr. Meredith Rosenthal* at 1–10 (docket no. 2495).[1]

**Analysis**

Plaintiff asks the Court to exclude two categories of opinions offered by Marshalek: those "related to pharmacy practice and dispensing obligations," and those "related to the conduct of federal regulators, in particular the Drug Enforcement Administration (DEA), and whether federal regulators caused or contributed to the opioids catastrophe." Motion at 1. The Court declines to exclude those opinions in their entirety, but limits them as set forth below.

**A. Marshalek's Opinions about Dispensing of Opioids by Pharmacies and Pharmacists**

Plaintiff argues that Marshalek lacks the requisite knowledge and experience to offer ***any*** opinions about the dispensing of opioids by Kroger's pharmacies and pharmacists, asserting he "has no meaningful experience in a pharmacy setting." Motion at 4. Plaintiff also points to Marshalek's lack of familiarity with Kroger's policies and procedures and his ignorance of the regulatory environment in which pharmacies operate. *Id*. at 7.

In response, Kroger stresses Marshalek's experience as a clinician and urges the Court to deny Plaintiff's motion because his opinions are based on "expertise as a medical doctor who treats

[1] *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3934597, at *1-5 (N.D. Ohio Aug. 20, 2019).

patients with opioid use disorder and as a prescriber of controlled substances." Response at 4. Kroger further argues that Marshalek's purported lack of familiarity with regulatory concepts such as red flags, due diligence, and corresponding responsibility does not disqualify him from offering "any opinions concerning pharmacies and pharmacists' dispensing of opioids." *Id*. at 5. Kroger maintains that Marshalek's "great knowledge of the United States healthcare system" provides an adequate basis under *Daubert* for him to testify that "pharmacists' position downstream from the prescriber prevents and limits the pharmacists' ability to question the legitimacy of prescriptions," and to explain that pharmacists face a disadvantage, as compared to physicians, in vetting patients for signs of addiction or prescription opioids use. *Id*. at 7.

The Court has carefully reviewed the parties' submissions, and agrees with Plaintiff that Marshalek lacks sufficient familiarity with pharmacy practice and the responsibilities imposed upon pharmacies and pharmacists by the CSA and its implementing regulations. Marshalek's deposition testimony makes clear he has not written any articles or given any presentations about "the obligations of pharmacies with respect to dispensing opioid prescriptions." Motion Ex. A. Marshalek Depo. at 39:16-23. Indeed, Marshalek admitted he could not recall ever hearing of the terms "corresponding responsibility," "red flags," or "due diligence" – all concepts of central relevance to the issues in this case. *See id*. at 16:16-19, 25:22 – 26:5. Given his level of knowledge, Marshalek may not opine on pharmacies' or pharmacists' scope of practice or the standard of care applicable to pharmacies or pharmacists, as those topics are beyond his expertise. *See CT1 Daubert Order re Lembke* at 13-14 (excluding Lembke's opinions concerning certain internal operations of pharmacies).[2]

[2] *In re Nat'l Prescription Opioid Litig.*, 2021, WL 4243084 at *7-8 (N.D. Ohio Sept. 17, 2021).

However, the Court does not agree with Plaintiff that Marshalek is not qualified to offer ***any*** opinions about Kroger's dispensing of opioids. "[R]egardless of the basis for the expert's qualifications, that a 'proffered expert may be unfamiliar with pertinent statutory definitions or standards is not grounds for disqualification. Such lack of familiarity affects the witness'[s] credibility, not his qualifications to testify.'" *Track One Daubert Order Regarding Dr. Meredith Rosenthal* at 4;[3] *see Davis v. Combustion Engineering, Inc.*, 742 F.2d 916, 919 (6th Cir. 1984); *First Tennessee Bank Nat. Ass'n v. Barreto*, 268 F.3d 319, 333 (6th Cir. 2001) (unfamiliarity with only some aspects of banking relationships merely affects weight and credibility, not admissibility).

This Court has previously permitted an academic psychiatrist to testify, to a limited extent, on the role of pharmacies in the opioid epidemic based on her experience as a prescriber. *See CT1 Daubert Order re Lembke* at 11.[4] There, the Court based its ruling, in part, on Dr. Lembke's "experience with thousands of interactions with pharmacies and pharmacists in a professional capacity, particularly in the context of prescribing controlled substances such as opioids." *Id.* at 12.[5] Similarly, Marshalek may offer his opinion, from the perspective of and based upon his experience as a physician, that pharmacists are at a "distinct disadvantage to question whether a prescription for opioids was written for a legitimate medical purpose because the pharmacist was not present when the prescription was written and would not know if the patient was actually examined by a medical doctor or simply handed the prescription by office staff." Response at 6; *See* Motion Ex. A Marshalek Depo. at 156:19 – 157:15. Plaintiff is free to cross-examine Marshalek to expose any limitations in his knowledge or the basis for his opinions.

[3] *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3934597, at *2 (N.D. Ohio Aug. 20, 2019).

[4] *In re Nat'l Prescription Opioid Litig.*, 2021, WL 4243084 at *7 (N.D. Ohio Sept. 17, 2021).

[5] *Id.*

**B. Marshalek's Opinions Regarding Regulation of the Opioid Industry by Federal Agencies**

Plaintiff next argues Marshalek should not be permitted to offer opinions about measures federal regulators could have taken "to limit the overall amount of prescriptions that ultimately contributed to the epidemic of overdose deaths." Motion at 9. Plaintiff maintains that "Dr. Marshalek has no demonstrated knowledge of or experience in the ways in which federal agencies regulate the opioid industry," and thus lacks any basis to support his opinions about federal agencies' regulatory decision-making and oversight. *Id.* at 9-10. Plaintiff contends Marshalek's experience as a DEA litigation consultant, which has been limited to criminal cases against pill mill doctors, "has no bearing on the role of federal agencies in regulating the opioid industry at large and provides no basis" for his opinions on that subject. *Id.* at 9. Plaintiff also notes that Marshalek, in his deposition, was unable to answer basic questions about the regulatory activities of the DEA and FDA. *Id.* at 8-9. Plaintiff highlights the following examples:

> Q: Do you know how the DEA or any other federal agency set manufacturing quotas for opioids?
>
> A: Not that I recall.
>
> * * *
>
> Q: Do you know how the federal government decided how opioids would be scheduled?
>
> A: I can't recall the specifics regarding that.

Motion Ex. A, Marshalek Depo. at 30:21-24; 31:6-10 (docket no. 4885-1).

> Q: Do you know how the FDA decides which indications to approve for opioid medications?
>
> A: I don't recall the specifics of that process.
>
> * * *

> Q: What do you recall about how the FDA decides which indications to approve for opioid medications?
>
> A: I recall just vague – what I do recall are just the phases of trials that medications need to pass through before they're at market and have indications, and that's rough and vague.
>
> Q: Okay. Do you recall or do you know anything more specific than that, about the FDA process?
>
> A: Not that I can recall at this moment.

*Id.* at 31:22 – 33:1 (docket no. 4885-1).

Kroger asserts that, "as an experienced DEA consultant, a controlled substance prescriber registered with the DEA, and an academic, Marshalek is more than qualified to assert these opinions." Response at 8-9. Kroger also notes Marshalek's opinions on federal regulation are based, in part, on the reference materials he reviewed. *Id.* at 9-10. In sum, Kroger argues Plaintiff's challenges to Marshalek go to the weight of his testimony, not its admissibility. *Id.* at 10.

Kroger is incorrect. Marshalek is simply not an expert regarding federal regulation of pharmaceuticals. His experience consulting for the DEA in pill mill cases, and his status as a drug-prescriber who has registered with the DEA (as has every doctor), add virtually nothing to his qualifications to opine on the *regulatory* issues involved in this case. While an expert is entitled to rely on research published by others to form the basis of his opinions, it is apparent from his deposition testimony that Marshalek's study and experience have not created real expertise on the federal regulation of opioids. In sum, the Court concludes Marshalek is not qualified to offer his opinions related to the conduct of federal regulators and whether federal regulators caused or contributed to the opioid epidemic. *See CT1 Daubert Order re Marketing Causation Opinions* at

11 n.5,[6] (citing *In re Welding Fume Prod. Liabl. Litig.*, 2005 WL 1868046, at *35 (N.D. Ohio Aug. 8, 2005) (a person does not become an expert in an area outside of her regular field merely by "reading up" for the specific purpose of testifying)).

**C. Marshalek's Conclusion Concerning Pharmacies' Responsibility for the Opioid Crisis.**

Marshalek concludes his report with the following paragraph:

> The federal government could have limited the amount of opioids manufactured, changed how opioids were scheduled, changed the FDA indication of opioid use, used [Risk Evaluation and Mitigation Strategies] or waiver requirements, or limited the manufacturer's ability to influence prescribing through marketing communication and other activities. To suggest that community pharmacies, or the pharmacists working for those community pharmacies, are responsible for the crisis of addiction is wrong.

Motion Ex. B, Marshalek Report at 4 (Docket no. 4885-2).

The Court concludes Marshalek may offer at trial the opinion set out in the first sentence quoted above, which is simply that the government *could have* done certain things. As noted above, however, Marshalek does not have the expertise to opine much further on the regulatory process.

Further, the Court holds Marshalek may not offer his final opinion: "To suggest that community pharmacies, or the pharmacists working for those community pharmacies, are responsible for the crisis of addiction is wrong." Marshalek's awareness of the practices of pharmacies and pharmacists are marginal at best, and certainly not those of an expert in the field. His CV is entirely devoid of any experience or expertise in pharmaceutical marketing or pharmacy procdedure, and he presents no methodology whatsoever to support a conclusion on causation. To allow him to offer an opinion that verges so closely upon an ultimate issue in this case would risk

[6] *In re Nat'l Prescription Opiate Litig*., 2019 WL 4054998 at *5 n.5 (N.D. Ohio Aug. 28, 2019).

confusing the jury, for "where one person sees speculation . . . another may see knowledge, which is why the district court enjoys broad discretion over where to draw the line." *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 672 (6th Cir. 2010); *see also Shahid v. City of Detroit*, 889 F.2d 1543, 1547-48 (6th Cir. 1989) (expert testimony found inadmissible where the proffered legal conclusion would confuse the jury and the opinions pertained to ultimate fact issues).

For the reasons provided, Plaintiff's Motion is **GRANTED** to the extent that Dr. Marshalek's testimony shall be limited as set forth above, and is otherwise **DENIED.**

**IT IS SO ORDERED.**

**/s/ Dan Aaron Polster May 26, 2023**
**DAN AARON POLSTER**
**UNITED STATES DISTRICT JUDGE**